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| 09/647,503      | 02/21/2001  | Samuel J. Tremont    | 2045.40PCT/US       | 7558             |

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EXAMINER

ZALUKAEVA, TATYANA.

ART UNIT PAPER NUMBER

1713

DATE MAILED: 01/15/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

**Office Action Summary**

Application No.

09/647,503

Applicant(s)

TREMONT, SAMUEL J.

Examiner

Tatyana Zalukaeva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2003 has been entered.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,471,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both disclose a delivery system that comprises a crosslinked polymer, a linker covalently bonded to a crosslinked polymer via the same groups, and an active ingredient that is covalently bonded to crosslinker, wherein the nature of covalent bonding between the linker and an active ingredient are identical in both the instant Application and U.S. 6,471,955.

#### ***Allowable Subject Matter***

4. Claims 15-20 are allowed over the prior art of record, subject to a Terminal Disclaimer as indicated above.
5. A telephone call was made by the Examiner to Applicants Attorney, Mr. Mandra, esq., on December 18, 2003 with suggestion to file the Terminal Disclaimer and put the claims in condition for allowance, however, such suggestion was declined.

#### ***Reasons for Indicating Allowable Subject Matter***

6. The following is an examiner's statement of reasons for allowance:

Drug delivery system comprising crosslinked polymer, active ingredient and specific linker are well known in the art. Thus Tremont (U.S. 5,827,925) discloses a

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drug delivery system adapted to release an effective amount of a drug at pH values of about 1 to 7 without releasing a significant amount of the drug at pH values of about 7 and above, the system comprising a polymeric material and a drug covalently bonded to the polymeric material (abstract). Suitable active ingredients which can be used in the practice of the invention herein include compounds which contain an hydroxyl ( $--OH$ ) group, a carboxylic acid group ( $--COOH$ ), an amino group ( $--NH$ .sub.2 or an  $--NHR$  group wherein R is an alkyl group of 1-4 carbons), a thiol group ( $--SH$ ), or an enolizable carbonyl group (i.e., aldehydes, ketones and amides) (col.3, lines 14-20). Polymeric materials which themselves cannot form such a covalent bond can be modified by attaching a linker group to such polymer. The linker group can be any suitable compound which can bond to both the polymer and the active ingredient. A covalent bond can be formed between the active ingredient and such attached linker group or the active ingredient can be covalently bonded to a linker group and the linker group/active ingredient attached to the polymer. Covalent bonds that can be cleaved under acidic conditions include bonds of the following types: silyl ethers and esters, acetals, thioacetals, imines, amins, carbonates, and vinyl ethers. A preferred covalent bond that can be cleaved within the preferred pH range is a silyl ether covalent bond. Silyl ether covalent bonds are especially preferred because such a bond can be formed between a silyl functional group on the polymer (or linker group) and an hydroxyl functional groups on the active ingredient (col.5, lines 40-57). A preferred polymer is a polymer selected from polyamine, polybutadiene, copolymers of 1,3-dienes and any

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polymer having a derivatizable olefinic bond. An especially preferred polymer is a polymer which is a functionalized polybutadiene containing amino functional groups. Such a polymer is preferred because the amino functional groups are capable of bonding with an active ingredient or a linker group. (col. 6, lines 9-20). The polymer may be crosslinked by crosslinking agents presented in col. 6, lines 42-47.

However, Tremont does not anticipate or suggest fairly that the covalent bond between the linker and polymer is a N-C or P-C covalent bond.

No other prior art that anticipates or suggests all the limitations of the instant claims has been located as of the date of this Office Action. Therefore, claims 15-20 are allowed over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (703) 308-8819. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703) 305-2450. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0651.



Tatyana Zalukaeva  
Primary Examiner  
Art Unit 1713

12/19/03

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